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(54) Title: BIO-DEGRADABLE MICROSPHERES FOR DIAGNOSING GASTROESOPHAGAL REFLUX

(57) Abstract: The invention provides a diagnostic composition for detecting both aspiration and gastroesophageal reflux comprising bio-degradable microspheres having a diameter of about 0.1-10 microns.

**AMENDED CLAIMS**

[received by the International Bureau on 10 March 2004 (10.03.04);  
original claims 1-8 replaced by amended claims 1-7;  
(1 page)]

**WHAT IS CLAIMED IS:**

1. A diagnostic composition for detecting pulmonary aspiration comprising bio-degradable polymeric microspheres having a diameter of about 0.1 - 10 microns wherein said polymeric microspheres are formed from polymeric materials selected from the group consisting of polyesters, polyphosphate esters, polyphosphazenes, polyorthoesters, polyanhydrides, polycarbonates and polyamides.
2. A diagnostic composition according to claim 1 wherein said bio-degradable polymeric microspheres have a diameter of about 1 - 4 microns.
3. A diagnostic composition according to claim 1 wherein said polyesters are selected from the group consisting of homopolymers and copolymers of lactic acid, glycolic acid, mandelic acid, caprolactone,  $\alpha$ -hydroxy acids, lactides and glycolides.
4. A diagnostic composition according to claim 1 comprising bio-degradable microspheres of polylactic acid.
5. A food product in combination with a diagnostic composition for detecting pulmonary aspiration said composition comprising bio-degradable polymeric microspheres having a diameter of about 0.1 - 10 microns.
6. The use of bio-degradable polymeric microspheres having a diameter of about 0.1 - 10 microns for the manufacture of a diagnostic composition for detecting pulmonary aspiration.
7. A diagnostic method for detecting pulmonary aspiration comprising providing a diagnostic composition comprising bio-degradable polymeric microspheres having a diameter of about 0.1 - 10 microns for oral administration in combination with food, wherein said microspheres are identifiable within the alveolar macrophages obtained by bronchoalveolar lavage.